



REVIEW

A Review of the Ahmed Glaucoma Valve Implant and Comparison with Other Surgical Operations

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ABSTRACT

The Ahmed glaucoma valve (AGV) is a popular glaucoma drainage implant used for the control of intraocular pressure in patients with glaucoma. While in the past AGV implantation was reserved for glaucoma patients poorly controlled after one or more filtration procedures, mounting evidence has recently encouraged its use as a primary surgery in selected cases. AGV has been demonstrated to be safe and effective in reducing intraocular pressure in patients with primary or secondary refractory glaucoma. Compared to other glaucoma surgeries, AGV implantation has shown favorable efficacy and safety. The aim of this article is to review the results of studies directly comparing AGV with

other surgical procedures in patients with glaucoma.

Keywords: Ahmed glaucoma valve; Glaucoma drainage implants; Glaucoma tubes; Glaucoma surgery; Ophthalmology; Trabeculectomy

INTRODUCTION

Glaucoma drainage implants (GDIs) have become a valuable tool for the surgical management of refractory glaucoma [1, 2]. GDIs have been demonstrated to be effective in reducing intraocular pressure (IOP) and are especially indicated in cases with high risk of failure after filtering procedures [3, 4]. Typically, GDIs are indicated for eyes that have already undergone one or more glaucoma surgeries, and for particular types of glaucoma in which filtering procedures are likely to fail (e.g., secondary glaucomas) [5–8]. The use of GDIs as a primary surgical procedure for glaucoma has also been investigated [9, 10]. Despite some concerns [11], early results are promising [12].

The Ahmed glaucoma valve (AGV), a GDI device, was approved by the FDA in 1993 for use in glaucoma patients with uncontrolled IOP [13]. Unlike the Molteno and Baerveldt implants, AGV provides a complex mechanism to control aqueous humor (AH) flow. Indeed, a

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valve mechanism has been introduced in an attempt to prevent complications sometimes encountered with non-valved GDIs, such as hypotony, shallow anterior chamber, choroidal effusion and choroidal detachment [14]. Several studies have shown that AGV is safe and effective in reducing IOP in patients with primary [15–17], secondary [18–24] and refractory glaucoma [25–27]. However, the hypotensive efficacy of AGV in comparison with other anti-glaucoma interventions has not been completely elucidated. The aim of the present review is to describe the results of studies directly comparing AGV and other IOP-reducing procedures in patients with glaucoma. This article is based on previously conducted studies and does not involve any new studies of human or animal subjects performed by any of the authors.

AHMED GLAUCOMA VALVE: DEVICE DESCRIPTION AND TECHNICAL DATA

AGV consists of three parts: (1) a plate which, depending on the model, is composed of medical grade silicone, polypropylene or polyethylene (Medpor; Porex, Atlanta, GA, USA; subsequently Stryker, Kalamazoo, MI, USA), (2) a drainage tube composed of medical grade silicone, and (3) a valve mechanism made of

medical-grade silicone (Fig. 1a). Polypropylene is a rigid, inflexible plastic, highly resistant to torsional forces, while silicone is a flexible rubber. Medpor is a porous high-density polyethylene which allows for rapid tissue integration and vascular ingrowth [28].

The adult model (S2) of AGV provides 184 mm² of total plate area, while the pediatric model (S3) provides a total area of 96 mm². Obviously, a smaller plate facilitates positioning in infants and subjects with a small eye. A variant of the device with two plates (total filtration area: 364 mm²), and one with a clip for pars plana tube insertion have also been designed. The recently introduced M4 AGV model has a total plate area of 160 mm² not including the surface area of pores (Table 1).

The valve mechanism of AGV consists of thin silicone elastomer membranes measuring 8 mm in length and 7 mm in width which create a Venturi-type chamber. The membranes are pre-tensioned to open and close so that, at least in principle, flow in response to IOP variations is ensured in the range of 8–12 mmHg [29]. After implantation, AH flows slowly and continuously into the trapezoidal chamber of the valve (Fig. 1b). As the pressure reaches the pre-set threshold value, the valve opens, thus decreasing the IOP. Since the inlet cross-section of the chamber is wider than the outlet, a pressure differential is created across the chamber. This pressure differential enables the

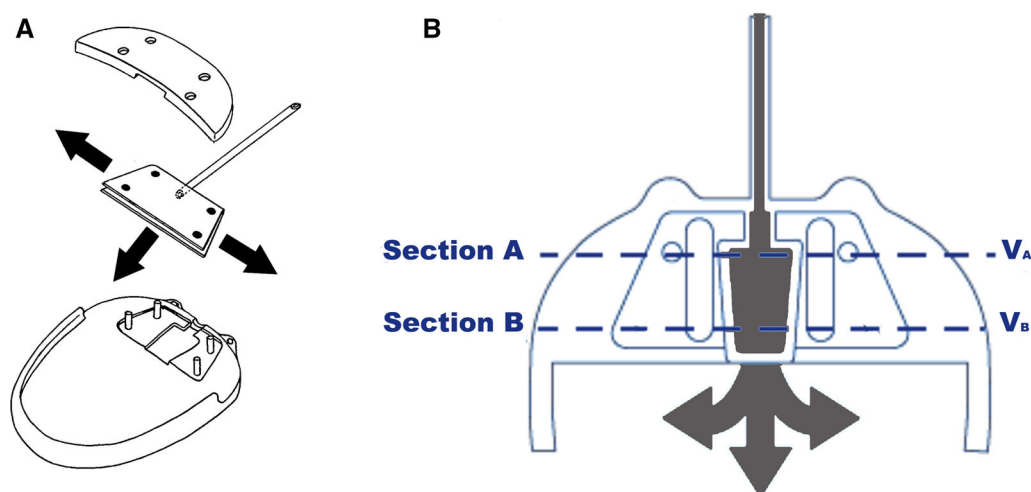


Fig. 1 Ahmed glaucoma valve. **a** Ahmed glaucoma valve components; **b** Ahmed glaucoma valve mechanism

Table 1 Ahmed glaucoma implants available models

Type	Model	Surface area (mm ²)	Material (plate)
Single plate	S2	184	Polypropylene
Single plate, pediatric size	S3	96	Polypropylene
Double plate	B1	364	Polypropylene
Single plate	FP7	184	Silicone
Single plate, pediatric size	FP8	96	Silicone
Double plate	FX1	364	Silicone
Single plate	M4	160	Polyethylene
Pars plana	PS2	184	Polypropylene
Pars plana, pediatric size	PS3	96	Polypropylene
Pars plana	PC7	184	Silicone
Pars plana, pediatric size	PC8	96	Silicone

valve to remain open even with a small pressure differential between the AC and the subconjunctival spaces surrounding the device. In order for Bernoulli's equation to be satisfied (fluid flowing into section A = fluid flowing out of section B; Fig. 1b), the velocity of the fluid has to increase as it leaves the chamber through the drainage tube. This increased velocity and the non-obtrusive flow account for better evacuation and smaller valve friction. The tension of the silicone membranes helps to reduce the risk of hypotony by closing the mechanism after the pressure has decreased to the desired level.

AHMED GLAUCOMA VALVE: COMPARISON WITH OTHER GLAUCOMA SURGERIES

Ahmed Glaucoma Valve Versus Trabeculectomy

Trabeculectomy is recognized as the gold-standard surgery for glaucoma against which other procedures are evaluated [5, 6, 30]. A comparison between AGV and trabeculectomy may be biased by the fact that different perceived indications for each procedure may result in

dissimilar groups being compared. For example, GDIs are frequently used as a second-line surgery after trabeculectomy has failed. Thus, when evaluating trials comparing trabeculectomy versus AGV implantation, special attention should be paid to sample characteristics.

Wilson et al. randomized 117 patients with primary open angle glaucoma (POAG), primary angle closure glaucoma (PACG) and secondary glaucoma to trabeculectomy ($n = 62$) or AGV implantation ($n = 55$) [31]. Totals of 44 of 62 eyes in the trabeculectomy group and 31 of 55 eyes in the AGV group had not undergone any prior surgical procedure for glaucoma. The mean follow-up time was 9.7 months, with a range of 6–13 months. After 1 year, the cumulative probability of success (IOP <21 mmHg and at least 15% IOP reduction from preoperative level) was 83.6% for the trabeculectomy group and 88.1% for the AGV group ($p = 0.43$). The AGV group required more frequently adjunctive medical therapy and the trabeculectomy group achieved significantly lower IOP from week 6 to 15 (12.6 vs. 16.4 mmHg) and from month 11 to 13 (11.4 vs. 17.2 mmHg).

Long-term results of AGV implantation versus trabeculectomy as initial surgical management in patients with POAG or PACG were later

investigated by the same authors [15]. The study enrolled 123 patients who were followed-up for 31 months. Totals of 64 patients were randomized to trabeculectomy and 59 to AGV. In the first postoperative year, the trabeculectomy group generally obtained lower pressures, but differences became statistically significant in the period between months 11 and 13. Subsequently, the IOP in the two groups became similar through months 41–52, and differences were not significant except from months 34 to 40, when the AGV group achieved lower pressures. When the authors applied the same criteria of success as in their first study, the cumulative probability of success was 68.1% and 69.8% at months 41–52 for the AGV group and the trabeculectomy group, respectively. No difference in the rate of complications was found between the two groups.

Tran et al. compared the efficacy of trabeculectomy and AGV in a group of patients with POAG, exfoliative glaucoma and pigmentary glaucoma [17]. Totals of 61 of 78 patients in the AGV and 61 of 88 patients in the trabeculectomy group had already undergone at least one procedure for glaucoma. Applying the same success criteria as in the previous studies (i.e.: IOP ≤ 21 mmHg and at least 15% IOP reduction from preoperative level), at 5 years there was no difference in cumulative success between the groups (36% vs. 48% for the AGV and the trabeculectomy group, respectively; $p = 0.094$). However, when more stringent criteria were used (IOP ≤ 18 , ≤ 15 and ≤ 12 mmHg, and a concomitant IOP reduction ≥ 20 , ≥ 25 and $\geq 30\%$ from baseline), trabeculectomy had significantly higher long-term probability of success than the AGV implant. The authors concluded that, when great IOP reduction and low IOP levels are needed, trabeculectomy achieves this goal more frequently. Doubts have been raised about the methodology of this retrospective study and in particular about the difference in visual acuity and IOP between the two groups at baseline (which may suggest that one group had less healthy eyes than the other) [32].

AGV and trabeculectomy were retrospectively compared by Shen et al. in a sample of 40 eyes with neovascular glaucoma (NVG) [33].

Surgical success was defined as an IOP ≤ 21 and ≥ 6 mmHg, with or without medications, and without the need of further glaucoma surgery. Only one eye (in the AGV group) had previously undergone a surgical procedure for glaucoma. Mean IOP values did not differ between the two groups at each visit follow-up, although the trabeculectomy group required a significantly greater number of medications at months 3 and 6. The respective cumulative success rates for the AGV and trabeculectomy groups were 90% and 85% at 6 months, 70% and 65% at 12 months, 60% and 60% at 18 months, and 60 and 55% at 24 months. No significant difference in the survival curves of the two groups was found ($p = 0.815$).

The advent of anti-vascular endothelial growth factor (anti-VEGF) drugs and their use as an adjuvant for glaucoma surgery in NVG has dramatically increased the success of trabeculectomy [34–36]. In a prospective interventional study, Liu et al. randomized 37 eyes of 36 patients with NVG to AGV implantation (19 patients) or combined trabeculectomy with intravitreal ranibizumab injection (18 patients) [37]. The administration of ranibizumab (0.5 mg) was done 1 week before trabeculectomy. Complete success was defined as an IOP ≥ 6 and ≤ 21 mmHg without any antiglaucoma medication or further glaucoma surgery. Partial success was defined as an IOP < 21 mmHg with topical antiglaucoma medications. In the combined trabeculectomy and ranibizumab group, 11 eyes (61.1%) achieved complete success, 6 eyes (33.3%) achieved partial success and 1 eye (5.6%) failed. In the AGV group, 11 eyes (57.9%) had complete success, 2 eyes (10.5%) had partial success, and 6 eyes (31.6%) failed. Complications were more common in the AGV group, especially in the early postoperative period (hypotony, shallow anterior chamber, hyphema). Although results from this study are exciting, additional studies with a larger sample size are needed to provide clear evidence about the optimal surgical treatment of NVG. Moreover, a clinical trial comparing the combination of AGV with ranibizumab versus the combination of trabeculectomy with ranibizumab would be useful.

Ahmed Glaucoma Valve Versus Ex-Press Shunts

The Ex-Press Mini Glaucoma Shunt (EXP) is a biocompatible, non-valved device developed by Optonol (Neve Ilan, Israel) to control IOP in glaucoma patients. Initially, EXP was implanted at the limbus so that the external portion of the device was only covered by the conjunctiva. This early technique was associated with a high rate of complications, including hypotony, erosion, extrusion and endophthalmitis [38–42]. To avoid these complications, a modified guarded technique was adopted, with the creation of a partial-thickness scleral flap covering the device at the limbus [43]. EXP was developed in an effort to make filtration surgery more straightforward. Nonetheless, it seems that the efficacy and safety profile of the EXP are not superior to standard trabeculectomy [44–47]. Only a few studies directly comparing AGV and EXP have been published.

Zhang et al. compared the efficacy and safety of EXP and AGV in a sample of 69 patients with refractory glaucoma (32 implanted with EXP and 37 with AGV) [48]. Qualified surgical success was defined as an IOP ≥ 5 mmHg and ≤ 21 mmHg, with or without topical glaucoma medications; complete surgical success was defined as an IOP ≥ 5 and ≤ 21 mmHg without any topical glaucoma medications. Baseline IOP was 36.6 ± 9.5 mmHg in the EXP group and 35.4 ± 9.1 mmHg in the AGV group. At the 9-month follow-up, patients implanted with EXP had qualified and complete success rates of 75% and 62.5%, respectively, and patients implanted with AGV had qualified and complete success rates of 62.1% and 51.3%, respectively ($p > 0.05$). No difference in postoperative complications was found between groups. Results from this study should be interpreted with caution, due to the short length of follow-up, the race of the patients (all patients were Asians) and the lack of information on baseline patient characteristics.

In a recent retrospective study, the efficacy of EXP and AGV was investigated in 64 eyes of 57 glaucoma patients (EXP implanted in 31 eyes and AGV in 33 eyes) [49]. At baseline, the AGV group had higher mean IOP (30.1 ± 10.4 vs. 23.5 ± 7.5 mmHg, $p < 0.01$), more

pseudophakic eyes (72.7% vs. 41.9%, $p = 0.02$) and a higher number of previous surgeries, including trabeculectomy, vitrectomy and keratoplasty ($p < 0.01$). Failure was defined as an IOP > 21 or ≤ 5 mmHg on two consecutive postoperative follow-up visits 3 months from surgery, reoperation for glaucoma or loss of light perception. Mean follow-up time was 2.6 ± 1.1 years in the EXP group and 3.3 ± 1.6 years in the AGV group. Failure rates were 16.1% in patients implanted with EXP and 24.2% in patients implanted with AGV ($p = 0.696$). A higher rate of complications was encountered in the AGV group (60.1%) than in the EXP group (32.3%). The results of this report should be interpreted with caution, due to methodological limitations and baseline differences between the two study groups.

Further trials directly comparing EXP and AGV are needed before more confident conclusions can be drawn. However, it is worth noting that the efficacy of EXP is typically affected by the same factors that limit the efficacy and prognosis of other filtration surgeries. Consequently, at least in theory, EXP may be a less-than-ideal option for secondary glaucomas at high risk of failure in which aggressive conjunctival healing and scarring is anticipated.

Ahmed Glaucoma Valve Versus Other Glaucoma Drainage Implants

Several glaucoma GDIs are currently available. Their characteristics differ in terms of size, shape, plate material and presence of a flow-limiting mechanism. Theoretically, a valve mechanism embedded in the implant may reduce postoperative hypotony-related complications. On the other hand, such a mechanism could limit AH drainage from the eye so that the efficacy of the implant would be compromised. Several comparison studies of AGV versus other implants have been published.

Ahmed Glaucoma Valve Versus Baerveldt Implant

Syed et al. retrospectively evaluated the efficacy of AGV and Baerveldt 350-mm² implant in

refractory glaucoma patients (64 eyes, 32 implanted with AGV and 32 with the Baerveldt device) [50]. Patients were matched for age, race, gender, glaucoma type, previous ocular history and preoperative IOP. A ligature with a 7.0 polyglactin suture was performed only in patients who underwent a Baerveldt implantation. The suture was tied around the tube 1–2 mm from the plate to limit filtration in the immediate postoperative period. During the first year from surgery, both the AGV and the Baerveldt group had a similar IOP profile. There was no significant difference in IOP between the two groups at any visit intervals. Success, defined as IOP decrease of at least 30% from baseline and IOP <22 mmHg with or without medications, was achieved in 25 of the 32 patients (75%) in the Baerveldt group and 24 of the 32 patients (75%) in the AGV group. The same rate of complications was recorded for both devices, with 3 patients (9.4%) in each group having complications that resulted in significant loss of vision or necessitated re-intervention.

Tsai retrospectively compared the efficacy and safety of AGV and Baerveldt implant in his personal single-surgeon series. Both medium-term (1 year) [51] and long-term (4 years) [52] results were reported. Surgical failure was defined as an IOP >21 or <6 mmHg at the last post-operative visit, reduction or loss of vision and additional surgical procedures. Totals of 70 patients underwent Baerveldt implantation (both 250- and 350-mm² plate models) and 48 patients underwent AGV implantation. Patients implanted with the AGV had lower mean IOP 1 day and 1 week ($p < 0.01$) after surgery. Afterward, no differences were observed in IOP from 1 to 48 months. No significant difference was found between AGV and Baerveldt implant survival curves ($p \geq 0.05$) up to 48 months of follow-up. The 1-, 2-, 3- and 4-year survival rates for AGV and Baerveldt groups were, respectively, 83 and 73% ($p = 0.183$), and 67% ($p = 0.359$), 71 and 64% ($p = 0.458$), and 62 and 64% ($p = 0.843$). Patients in the Baerveldt group were more likely to develop early postoperative hypotony-related complications and failure, whereas patients in the AGV group were more likely to be on additional glaucoma medications

(starting at 18 months post-surgery) and to develop later failure. These results should be interpreted cautiously, considering the retrospective nature of the study and the absence of patient matching at baseline. Patients in the AGV group were older at baseline (69.2 vs. 62.3 years; $p = 0.032$), were more likely to have a diagnosis of glaucoma associated with inflammation (20.8% vs. 4.3%, $p < 0.01$) and had a higher pre-operative mean IOP (38.5 vs. 34.6 mmHg; $p = 0.032$).

The Ahmed versus Baerveldt study (AVB study) was a prospective, multicenter, randomized clinical trial comparing AGV (model FP7) and Baerveldt 350-mm² implants in patients affected by refractory glaucoma [53]. Surgical procedures were standardized in all the centers involved in the study. No manipulation to limit filtration was performed in the AGV group, while a releasable intraluminal nylon cord or a polyglactin ligature suture was placed in the Baerveldt devices that were implanted. Patients were scheduled to be followed-up until 5 years and failure was prospectively defined as uncontrolled IOP (IOP >18 or <5 mmHg or IOP reduction from baseline <20% in two consecutive visits at or after 3 months), additional glaucoma surgery, or loss of light perception. Between October 2005 and March 2009, 238 patients were randomized to AGV ($n = 124$) or Baerveldt ($n = 114$) implantation. The mean number of previous surgical procedures was the same between the two groups. Overall, the mean number of previous interventions was 1.7 ± 1.2 , the most common being cataract extraction (172 patients, 72%), trabeculectomy (89 patients, 37%), pars-plana vitrectomy (34 patients, 14%) and penetrating keratoplasty (19 patients, 8%). Only 27 patients had no previous surgery performed (11%) [53]. At 1-year follow-up, failure had occurred in 51 patients (43%) in the AGV group and 30 patients (28%) in the Baerveldt group ($p = 0.02$) [54]. The cumulative probability of failure was 43% in the AGV group and 28% in the Baerveldt group ($p = 0.049$). At 3-year follow-up, failure had occurred in 63 patients (51%) in the AGV group and 39 patients (34%) in the Baerveldt group ($p = 0.013$) [55]. The cumulative probability of failure at 3 years was 51% in the AGV group and

34% in the Baerveldt group ($p = 0.03$). Regarding the IOP, from month 1 onward, the Baerveldt group had lower IOP values than the AGV group, which reached statistical significance at the 12- and 18-month time-points ($p < 0.01$, Fig. 2a). Mean IOP at 3 years was 15.7 ± 4.8 mmHg in the AGV group and 14.4 ± 5.1 mmHg in the Baerveldt group. Although both groups had similar complication rates, the Baerveldt group experienced more frequently hypotony-related vision-threatening complications than the AGV group (6 vs. 0%, $p < 0.01$). The authors concluded that, although both devices are effective in reducing IOP in patients with refractory glaucoma, the Baerveldt implant achieves success in a higher percentage of cases, at the cost of a higher rate of hypotony-related complications.

The Ahmed Baerveldt Comparison study (ABC) was a randomized, multicenter, controlled clinical trial designed to prospectively compare the safety and efficacy of these two commonly implanted GDIs [56]. A total of 276 patients were enrolled by 16 centers worldwide between October 2006 and April 2008. Totals of 143 patients were randomized to AGV (model FP7) and 133 to Baerveldt implantation (350-mm² plate). All operations were performed by experienced surgeons using the same standardized technique. The tube of the Baerveldt GDI was totally occluded in order to restrict AH flow until encapsulation of the plate was achieved. The primary outcome measure was failure, defined as follows: (1) IOP >21 mmHg or

IOP reduction $<20\%$ from baseline in two consecutive visits (at least 3 months after surgery); (2) IOP <5 mmHg in two consecutive visits (at least 3 months after surgery); (3) additional glaucoma surgery including the removal of the implant; and (4) loss of light perception. Most common diagnoses at baseline were POAG (40%), NVG (29%), PACG (7%) and uveitic glaucoma (7%). Forty-two percent of patients had previously undergone trabeculectomy, while 20% of patients had no incisional surgery at enrollment. Results of the study were reported at 1, 3 and 5 years [57–59]. In the AGV group, IOP was reduced from 31.2 ± 11.2 mmHg at baseline to 15.4 ± 5.5 and 14.3 ± 4.7 mmHg at 1-year and 3-year follow-up, respectively [57, 58]. In the Baerveldt group, IOP was reduced from 31.8 ± 12.5 mmHg at baseline to 13.2 ± 6.8 and 13.1 ± 4.5 mmHg at 1-year and 3-year follow-up, respectively [57, 58]. At 5 years, after censoring for patients who underwent additional surgery or loss of light perception, IOP was reduced from 29.6 ± 10.1 at baseline to 14.7 ± 4.4 mmHg in the AGV group and from 28.3 ± 9.3 at baseline to 12.7 ± 4.5 mmHg in the Baerveldt group [59]. The AGV group achieved lower IOP at 1-day and 1-week visits; however, mean IOP in the Baerveldt group was approximately 1–2 mmHg lower thereafter, except at the 2-year visit (Fig. 2b). The cumulative probability of failure was 44.7% in the AGV group and 39.4% in the Baerveldt group at 5 years ($p = 0.65$). While the total number of

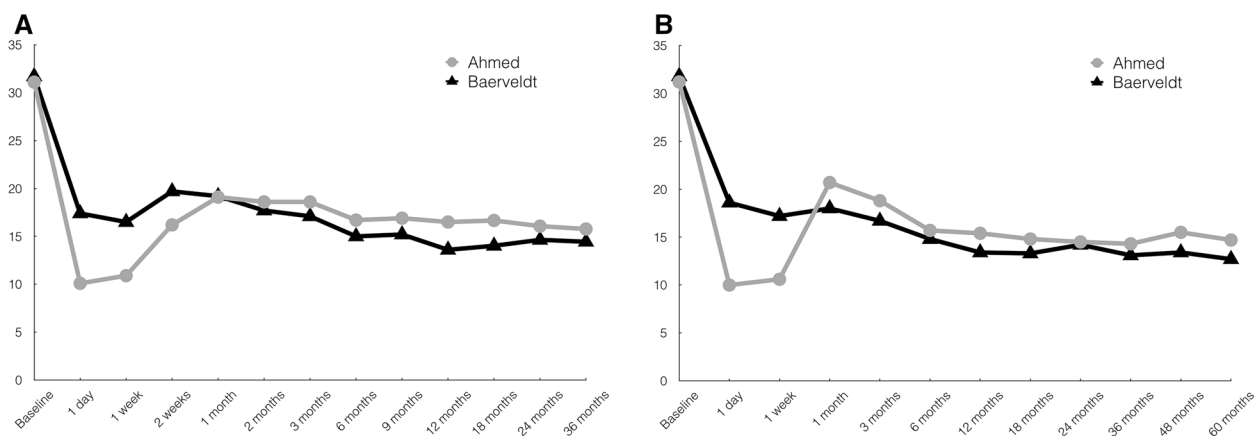


Fig. 2 Mean intraocular pressure in the Ahmed versus Baerveldt Study (a) and in the Ahmed Baerveldt Comparison Study (b)

failures was similar, the reasons for failure were different between groups. Failure due to uncontrolled IOP or reoperation was recorded in 46 eyes of the AGV group and in 25 eyes of the Baerveldt group ($p < 0.001$). Only 11 eyes experienced persistent hypotony or loss of light perception in the AGV group, compared to 22 eyes in the Baerveldt group. No difference in the rate of complications was found at 5 years [60], with late complications developing in 56 patients in the AGV group and in 67 patients in the Baerveldt group ($p = 0.082$). However, tube occlusion ($p = 0.037$) and phthisis bulbi ($p = 0.037$) occurred more frequently in the Baerveldt group. Other complications resulting in reoperation or vision loss were also more common in the Baerveldt group ($p = 0.034$).

A recent meta-analysis by Wang et al. compared the efficacy and safety of AGV and Baerveldt GDIs in patients with glaucoma [61]. Ten controlled clinical trials (1048 eyes) were included in this meta-analysis, involving 2 randomized clinical trials and 8 retrospective comparative studies. Short-term and long-term results were analyzed separately. Definition of success was consistent with the original studies, and a criterion of IOP < 21 mmHg was adopted. Over the short term (714 eyes), the success rate was 78.6% and 79.7% (OR 0.97, $p = 0.90$) for the AGV and the Baerveldt groups, respectively, while over the long term (835 eyes), the success rate was 59.2 and 68.4% (OR 0.73, $p = 0.04$) for the AGV and the Baerveldt groups, respectively. The AGV group had higher IOP values than the Baerveldt group both over the short term (6 studies, 685 eyes, weighted mean difference: 2.12 mmHg; 95% CI 0.72–3.52; $p < 0.05$) and the long term (7 studies, 659 eyes, weighted mean difference: 1.85 mmHg; 95% CI 0.43–3.28; $p = 0.01$). However, eyes in the AGV group experienced overall fewer complications (OR 0.67; 95% CI 0.50–0.90; $p < 0.01$), and especially fewer serious complications (OR 0.57; 95% CI 0.36–0.91, $p = 0.02$).

Ahmed Glaucoma Valve Versus Molteno and Krupin Implant

In an earlier study, Ayyala et al. compared the efficacy of the double-plate Molteno GDI versus

the efficacy of the AGV [62]. In their retrospective, case-control study, 60 advanced glaucoma patients matched for age, diagnosis, and previous surgeries underwent Molteno GDI (30 patients) or AGV implantation (30 patients). Minimum follow-up was 6 months and success was defined as follows: (1) IOP < 22 and > 4 mmHg; (2) a decrease of no more than 2 lines in visual acuity; and (3) no additional surgery to control IOP. At the 12- and 24-months follow-up, there was no difference in the rate of success between the two groups (73 and 56% for the Molteno group and 60 and 50% for the AGV group, at 12 and 24 months, respectively, $p = 0.72$). Nevertheless, IOP was significantly lower in patients implanted with the Molteno GDI at both time-points. At 12 and 24 months, mean IOP was 13.36 ± 5.2 and 13.3 ± 5.1 mmHg in the Molteno group, and 16.7 ± 5.6 and 19 ± 5.8 in the AGV group ($p = 0.026$ and $p < 0.01$ for the comparisons at 12 and 24 months, respectively).

The efficacy of the AGV and the single-plate Molteno GDI were compared in patients with NVG in a study by Yalvac et al. (65 patients, 38 with AGV and 27 with Molteno GDI) [20]. Patients were matched for age, pre-operative IOP, gender and follow-up. Surgical success was defined as an IOP < 22 and > 5 mmHg, without additional glaucoma surgery and no loss of light perception. Patients using topical medications for IOP control were not considered failures. The overall success rates of the AGV were 63.2% at 1 year, 56.1% at 2 years, 43.2% at 3 years, 37.8% at 4 years and 25.2% at 5 years. The success rates of the Molteno GDI were 37%, 29.6%, 29.6%, 29.6% and 29.6%, respectively at the 1-, 2-, 3-, 4- and 5-year follow-ups. Although success rates were always higher in the AGV group, the log-rank test indicated no significant difference between survival curves ($p = 0.141$). Patients implanted with the Molteno GDI had more complications, especially hypotony-related, in the early postoperative phase. Choroidal effusion was encountered in 5 eyes (18.5%) in the Molteno group and 2 eyes (5.3%) in the AGV group, shallow anterior chamber was seen in 4 eyes (14.8%) in the Molteno group and 2 eyes (5.3%) in the AGV group, and 1 case

of suprachoroidal hemorrhage was observed in the Molteno group (3.7%).

In a prospective, randomized, multicenter study with a follow-up of 2 years, Nassiri et al. compared the efficacy of the AGV (FP7 model) and the Molteno GDI in a series of patients with refractory glaucoma [63]. The study included 46 eyes randomized to AGV and 46 eyes randomized to Molteno GDI implantation. Treatment success was defined as IOP between 6 and 21 mmHg, while failure was defined as IOP >21 mmHg on maximally tolerated medical therapy or IOP <6 mmHg on 2 consecutive visits. Phthisis bulbi, loss of light perception, devastating complications or reoperation were considered failures. Cumulative probabilities of success at 1 and 2 years were 88% and 82% in the AGV group and 93% and 84% in the Molteno group (log-rank test, $p = 0.65$). While IOP was significantly lower in the AGV group compared to the Molteno group at postoperative day 1 and week 1, the Molteno group had significantly lower pressures thereafter, up to 24 months. Complication rates were comparable in the two groups and no case of persistent hypotony or devastating complication was encountered.

The efficacy and safety of the double-plate Molteno, the Krupin implant and the AGV were compared in a retrospective study by Taglia et al. [64]. A total of 27 Molteno, 13 Krupin and 13 AGV implantations were included in this study. The patients were matched for age and diagnosis at baseline. However, patients in the AGV group had higher IOP and used more glaucoma medications than the other groups at baseline. Two criteria of success were adopted: (1) IOP >6 and <15 mmHg 3 months after surgery (medications permitted) without additional filtration surgery and without tube removal; and (2) IOP >6 and <21 mmHg 3 months after surgery (medications not permitted) without additional filtration surgery and without tube removal. The Molteno group was significantly more likely than the AGV group to satisfy the first criterion of success ($p < 0.01$, log-rank test), while a similar but statistically non-significant tendency was observed with the second criterion of success. After 1 year, success rates according to the first

and the second criterion were, respectively, 80% and 57% for the Molteno group, 39% and 46% for the Krupin group and 35% and 25% for the AGV group. None of the patients in the AGV group had complications requiring reintervention. Thirteen of 27 patients (48%) in the Molteno group required additional surgery, in most cases during the first 3 months of follow-up (11 of 13 patients). Complications requiring re-intervention were generally related to hypotony despite the temporary ligation of the tube. Seven of 13 patients (54%) in the Krupin group had complications requiring re-intervention; 5 of these complications were hypotony-related. The results of this report should be interpreted with caution due to the small sample size and the retrospective nature of the study.

Ahmed Glaucoma Valve Versus Cyclodestructive Interventions

Cyclodestructive procedures have traditionally been reserved for eyes with refractory glaucoma and limited visual potential [65–68]. Immediate and late complications of these procedures include pain, visual acuity reduction, corneal edema, persistent hypotony and phthisis bulbi [69, 70]. An endoscopic technique which allows direct visualization and laser treatment of the ciliary body has been described [71]. Such an endoscopic cyclophotocoagulation (ECP) device combines a laser source, an endoscope, and an illumination beam in the same probe [68, 70, 72]. The technique appears promising in terms of efficacy and safety [68, 70, 73].

In a study by Yildirim et al., 66 patients with NVG and visual acuity of hand motion or worse were randomized to AGV or transcleral diode cyclophotocoagulation [69]. A minimum 24-month follow-up was available for 58 of the 66 patients. Success was defined as an IOP <21 and >5 mmHg without additional glaucoma surgery and without loss of light perception. Post-operative medications were allowed and not considered a failure. Preoperative IOP was 43.4 ± 11.9 mmHg in the cyclophotocoagulation group and 43.3 ± 7.4 mmHg in the AGV group ($p > 0.05$). At 24 months, the IOP decreased to 18.72 ± 13.5 and 22.88 ± 7.3 mmHg in the transcleral

cyclophotocoagulation and AGV groups, respectively ($p > 0.05$). Success rates at 24 months were similar in the two groups (61.18% and 59.26% for the cyclophotocoagulation and AGV groups, $p > 0.05$). The most frequent complications in the cyclodestructive group were anterior segment inflammation (5 eyes, 20%), neurotrophic keratitis (2 eyes, 8%) and hypotony (3 eyes, 12%). In the AGV group, hyphema was encountered in 5 eyes (15%) and tube occlusion in 3 eyes (9%). No devastating complications were noted in either group.

The safety and efficacy of ECP through the pars plana versus AGV were compared in a prospective study by Lima et al. [74]. Sixty-eight patients were randomized to ECP ($n = 34$) or AGV implantation ($n = 34$). To be eligible for inclusion patients had to be pseudophakic with IOP ≥ 35 mmHg on maximum tolerated medical therapy, have undergone at least 1 previous trabeculectomy, and have visual acuity better than light perception. Success was defined as IOP > 6 and < 21 mmHg at 24 months with or without medications. Preoperative IOP was 41.32 ± 2.03 mmHg in the AGV group and 41.61 ± 3.42 in the ECP group. At the 24-month follow-up, the IOP was reduced to 14.73 ± 6.44 and 14.07 ± 7.21 in the AGV and ECP groups, respectively ($p = 0.07$). Success at 24 months was similar in the two groups: 70.58% in the AGV group and 73.52% in the ECP group ($p = 0.5$). Interestingly, eyes in the AGV group had a greater incidence of visual acuity decline at 24 months. In the AGV group, a higher rate of complications was encountered, including choroidal detachment (17.64%) and shallow anterior chamber (17.64%). It should be noted that, in this study, laser treatment was performed along the full length of the ciliary processes and the anterior third of the pars plana over 210° . This rather extensive coagulation may have accounted for the favorable ECP results. Further studies with more patients and longer follow-up are needed to clarify the role of ECP in the treatment of patients with refractory glaucoma.

CONCLUSION

The role of GDIs has been traditionally limited to patients with refractory glaucoma and

patients with high risk of failure after standard filtering surgeries. The existing evidence seems to suggest that AGV might have a more favorable safety profile when compared to non-valved GDIs [20, 51, 52, 54, 55, 60, 61, 64]. On the other hand, non-valved GDIs seem to achieve lower pressures than the AGV [54, 55, 57–59, 62–64]. AGV is a useful surgical choice and represents a reasonable compromise between efficacy and potential surgery-related complications. Due to its safety profile, AGV may be considered as the initial surgery in those glaucomas that are more prone to failure after standard filtering procedures. However, even in these cases, the risk-benefit ratio has to be carefully weighted and discussed with the patient. In conclusion, the existing literature suggests that the currently available AGV is probably the GDI that offers the most favorable risk-efficacy profile.

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Data Availability. Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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